

**REMARKS**

Claims 1-21 are currently pending in the present application and under examination on the merits. Claims 1 and 12 are the only pending independent claims.

Claims 23-26 have been cancelled, without prejudice or disclaimer, in this amendment to advance the prosecution and allowance of this application.

**Propriety of Amendment After Final Rejection**

It is believed that this Amendment After Final Rejection will place the application in condition for allowance, or at the least, place the claims as amended herein that have not been canceled herein, in better condition for an appeal. Moreover, in view of prior amendments, prior requests for consideration, and two Declarations of Dr. Henrich Cheng, the sole inventor and named Applicant, as well as a telephone interview with the Examiner, it was believed that the claims as pending prior to this Amendment After Final Rejection were sufficient to result in an allowance. Therefore, the amendments made herein were not presented earlier. In view of the foregoing, Applicant respectfully submits that the requirements for entry of this Amendment under 37 C.F.R. § 116 have been met, and respectfully requests that entry of this Amendment After Final Rejection be entered. If the foregoing amendments do not place this application in condition for allowance, a prompt Advisory Action is respectfully requested.

**Explanation of and Support for the Amendments**

For clarity, without prejudice or disclaimer, claims 1, 2, and 12 have been amended in order to more particularly point out and distinctly claim the subject matter that Applicant regards as his invention, as directed to a functional treatment for avulsion of a nerve root between the central nervous system and the peripheral nervous system, or avulsion of the peripheral nervous system in a living vertebrate. Independent claims 1 and 12 now provide for a functional connection between two avulsed ends of the peripheral nervous system to the central or two avulsed ends of the peripheral nervous system, without an intermediate graft. These amendments also further clearly distinguish the present invention from the prior art.

The amendments are supported by the second full paragraph at page 2, the first and third full paragraphs at page 3, and Example 4 of the application as filed. The “living vertebrate” recitation is supported at least by Example 4, starting at page 13 of the application as filed, where the present invention is demonstrated on living rats which evidenced less impairment with the

present invention using the fibrin glue mixture of the present invention including the growth factor than treatment of living rats using a fibrin glue mixture without the growth factor, signifying acceptable nerve repair. The recitation “without an intermediate graft” is supported by the procedure described with respect to Example 4, particularly the first two paragraphs of page 13 after the Example 4 heading, where no intermediate graft is used between the severed ends of the sciatic nerve in living rats as appropriate laboratory models of vertebrates, in comparison with the procedure described in the paragraph bridging pages 8 and 9 of the application as filed, where an intermediate graft was used to extend between different portions of nervous systems in living rats. An aspect relating to intermediate grafts had been recited in claim 23-26, which have now been canceled in the present amendment to advance the prosecution of this application to allowance.

Accordingly, the amendments made herein introduce no new matter, and entry of the amendments is proper and respectfully requested.

### **Claim Rejections 35 USC § 103**

Claims 1-21 and 23-26 were rejected under 35 USC §103(a) as being unpatentable over Cheng et al., U.S. Patent 6,235,041 (“Cheng”) in view of Schenck *et al.*, US Patent 4553542 (“Schenck”). As explained previously, Applicant in the present invention is the same Dr. Henrich Cheng of the Cheng reference and therefore, is very familiar with the significant differences between the subject matter of the present application and the subject matter disclosed and claimed in Cheng.

At page 2 of the Detailed Action, the Examiner referred to Applicant’s prior arguments that the Cheng grafts are not viable, but characterized Cheng as teaching the use of grafts that comprised multiple intercostal nerves which were part of the peripheral nervous system and pointed out that the claims “fail to specifically claim viable/living portions of the peripheral nervous system,” and concluded that the previous claims read on Cheng’s use of the grafts, even though they are not viable.

The claims as amended herein clearly support the interpretation that portions of the avulsed peripheral nervous system connected to the avulsed portion of the central nervous system or the peripheral nervous system of the living vertebrate by the claimed fibrin glue

mixture recited in the claims must involve living tissue and the fibrin glue mixture, since there are no intermediate grafts involved between the tissue, which is necessarily living tissue, of the live vertebrates being treated by the method of the present invention.

Cheng failed to teach connecting a viable or living portion of the peripheral nervous system of a live vertebrate with any portion of the central nervous system or any portion of the peripheral nervous system, other than through the separately removed and grafted nerve bundle that was not viable, that in effect, served merely as a bridge or conduit in Cheng. In currently amended claims 1, 2 and 12, the claimed subject matter now clearly points out the feature of the invention responsible for the functional treatment in a vertebrate for avulsion of a nerve root between the central nervous system and the peripheral nervous system, or avulsion of the peripheral nervous system in a live vertebrate using the vertebrate's own nervous system tissue and the claimed fibrin glue mixture, and not a separate intermediate graft. This should now be definitely and very clearly patentably distinct from Cheng, which requires the use of the non-viable intermediate grafts.

In the specification as filed, it is indicated that the present invention is based on the discovery that avulsions between the central and peripheral nervous systems can be repaired using a fibrin glue mixture to restore the functional connection of the avulsed ends in the second full paragraph at page 2; that the present invention features a method of functionally reconnecting an avulsed nerve root to the spinal cord to be connected in a vertebrate (in the first full paragraph at page 3); and that the present invention features a method of functionally connecting the proximal and distal ends of a peripheral nerve in a vertebrate (in the third full paragraph of page 3). The treatment method for avulsion in a vertebrate according to the invention should certainly be subjected to the viable/living portions of the nerves, which is also supported by Example 4 of the application, wherein viable and living rats were used for demonstrating the efficacy of the method according to the present invention. Therefore, currently amended claims 1, 2 and 12 are different from and would have been non-obvious over Cheng alone or in view of Schenck at the time of the present invention.

Schenck taught an anastomosis device and method for using it to join a tubular anatomical structure that is supported with the body by connective tissue and has a prepared open end to a second anatomical structure, such as blood vessels, fallopian tubes, ureters, vas

deferens and outer nerve sheaths (see abstract and claim 1). The use of Schenck's encircling anastomosis device would not be useful for, and therefore is totally irrelevant to a method for connection between nerves, which are not hollow tubes. What might work for connecting nerve sheaths may not be effective in connecting nerves. Cheng and Schenck are not properly combinable, because of the different structure and functions of nerves involved in Cheng, compared to the anatomical structures repaired in Schenck. Even assuming only for the sake of argument that these references are properly combinable, as refuted previously, the combination does not teach or suggest the presently claimed invention, especially since Schenck's anastomosis device is yet another intermediate structure between and contrary to the living nervous tissue being joined by the fibrin glue mixture as now claimed in the present application, and is therefore further distinguished from the present invention.

Since currently amended claims 1 and 12 should be allowable, dependent claims 2-11 and 13-21 should be allowable. Furthermore, claims 23-26 are cancelled. Accordingly, the rejection is now moot. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) for obviousness over Cheng in view of Schenck are respectfully requested.

It is now believed that this application is in complete condition for allowance, and an early Notice of Allowance is respectfully requested.

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If for some reason the application is not considered to be in complete condition for allowance, the Examiner is requested to contact the undersigned attorney to discuss ways of achieving such allowance.

Respectfully submitted,

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(Date)

By:



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